UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,504	03/05/2007	Atsuko Fukui	MATOB1.001APC	4157

20995 7590 05/12/2011

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
05/12/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
efiling@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/571,504	FUKUI, ATSUKO	
	Examiner	Art Unit	
	NISSA WESTERBERG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments, filed February 23, 2011, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 3 - 5, 7, and 10 – 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, and 5 - 12 of copending Application No. 12/682747. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 23, 2010 and those set forth below.

Applicant traverses this rejection on the grounds that none of the claims are unpatentable over the above cited references but if necessary, will consider filing a terminal disclaimer.

This argument is unpersuasive. Even in view of the amendments to the claims, the claims of US'747 still require the presence of all the ingredients recited in the instant claims and the presence of at least one type of taste adjusting ingredient. Therefore the claims of US'747 still anticipate the claims of the present application.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 states that the jelly drink comprises aggregated jelly granules. It is unclear if the maximal length for the jelly granules recited in lines 2 – 3 of claim 5 refers to the length of the individual jelly granules prior to aggregation or to the length of the aggregated jelly granules made from smaller sized individual granules. Please clarify.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1, 4 – 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagami et al. (WO 00/54811; all citations from US 2005/0152975, a continuation of the PCT application) in view of Fukui et al. (US 6,277,395). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 23, 2010 and those set forth below.

In regards to the newly rejected claims, Nakagami discloses sitafloxacin, an antibiotic that contains a basic material and contains a nitrogen in an amine group (p 3, col 2, next to last structure, lower left corner), as a drug with a disagreeable taste that can be delivered using the composition. Among the sugar alcohol that can be used in the composition are erythritol, xylitol, sorbitol, maltitol or mixtures thereof (¶ [0055]). Fukui et al. discloses that the viscous preparation to be drunk should have a jelly strength at 20℃ between 10 to 100 g/cm^2 to be thick enough to avoid misswallowing of the medicine such as tablets, capsules, granule or powders but not so thick as to be difficult to swallow (col 3, ln 44 – 45; col 4, ln 28 – 40). There is no evidence currently on record that the jelly granules produced when the powder of Nagasaki are dispersed in water do not have the claimed maximum length of 1 - 10 mm.

Applicants traverse this rejection on the grounds that neither reference teaches a jelly drink that comprises aggregated jelly granules. Nakagami teaches a drug dispersed uniformly within wax particle, which are not aggregated jelly granules. Fukui also fails to

teach this feature as it teaches a mixture of water an adhesive paste that takes the form of a viscous liquid or gelatinoids at room temperature.

These arguments are unpersuasive. In looking to the instant application to see how such a product is formed, the same compositions as are taught in the applied prior art as taught as providing a granular jelly drink. Namely, powders are dispersed in water by both Nagasaki and the instant application.

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagami et al. in view of Fukui et al. as applied to claims 1, 4 – 8 and 11 above, and further in view of Yu et al. (US 2003/0064107).

Nakagami et al. discloses granular pharmaceutical compositions that mask the disagreeable taste of the drug and provides a favorable sensation upon oral administration (¶ [0001]). The addition of a sugar alcohol to the drug and wax substance provides a formulation with excellent ability to mask the taste and provide a favorable sensation (¶ [0007]). The waxes that can be used are hydrogenated oils such as the vegetable oils soybean and rape seed; fats and oils of vegetable or animal origin; fatty acids and derivatives such as fatty acid glycerin esters and fatty acid sucrose esters and mixtures of two or more of these substances (¶ [0054]). These waxes read on the bitterness masking component of the instant claims. A composition such as taught by Fukui containing a gelatinizing component as taught by Fukui makes swallowing of the powder easier.

Neither reference discloses disclose macrolide antibiotics as medicaments to be taste masked.

Yu et al. discloses that macrolide antibiotics have an unpleasant taste are among the active medicaments that are useful in a taste masked liquid formulation ([0009]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use a macrolide antibiotic as the bitter tasting medicine in the granular medicinal compositions of Nakagami. The person of ordinary skill in the art would have been motivated to make those modifications to prepare an antibiotic composition for the treatment of bacterial infections and reasonably would have expected success because Nakagami discloses a wide variety of medications having an offensive taste can be masked using such compositions.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fukui et al. (US 6,277,395) in view of Nakagami et al. (WO 00/54811; all citations from US 2005/0152975, a continuation of the PCT application) and Gowan, Jr. et al. (US 5,374,659).

Fukui et al. discloses a swallowing assistive drink that improves the swallowing of medicines substitutable with ordinary water that does not disturb the efficacy of the medicine (col 1, ln 47 – 52). The medicine is taken together with the swallowing assistive drink (col 1, ln 65 – 67). Thus, Fukui et al. discloses medicine free compositions that are combined with the medicine by the user. As such, the jelly drink would be packaged without the medicine. The swallowing assistive drink contains a

substance the gels such gums or agar (col 3, ln 30 – 39) and sugar alcohols such as mannitol or erythritol (col 4, ln 1 – 2). In the examples, a variety of gelation agents; erythritol or mannitol, flavor and water are disclosed (col 5, ln 8 – 20; col 6, ln 1 – 15).

Fukui does not disclose the presence of a bitterness masking component of at least one of a vegetable fat, vegetable oil, animal fat or animal oil drink that does not contain the medicament.

Nakagami et al. discloses granular pharmaceutical compositions that mask the disagreeable taste of the drug and provides a favorable sensation upon oral administration (¶ [0001]). The addition of a sugar alcohol to the drug and wax substance provides a formulation with excellent ability to mask the taste and provide a favorable sensation (¶ [0007]). The waxes that can be used are hydrogenated oils such as the vegetable oils soybean and rape seed; fats and oils of vegetable or animal origin; fatty acids and derivatives such as fatty acid glycerin esters and fatty acid sucrose esters and mixtures of two or more of these substances (¶ [0054]). These waxes read on the bitterness masking component of the instant claims. The wax is melted and the drug is dissolved or dispersed therein (¶ [0057]).

Gowan, Jr. et al. discloses an aqueous pharmaceutical suspension of a water insoluble pharmaceutical active agent; xanthan gum in an amount to stabilize the suspension; starch and polyoxyethylene sorbitan monooleate; and an effective amount of a taste masking composition and water (col 2, ln 15- 25). Among the active agents that can be used in the formulation is the macrolide antibiotic erythromycin estolate (col 3, ln 45).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate a fat or oil in combination with sugar alcohol to mask the taste of the bitter medicament. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Gowan, Jr. et al. discloses that the bitter tasting medicine need not be directly coated with the taste masking, as in Nakagami, but rather can be contained in the medium surrounding the drug. The swallowing assistive drink of Fukui acts as the carrier with the user providing the drug to be masked to form a taste masked suspension like that taught in Gowan, Jr. et al.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NISSA WESTERBERG whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nissa M Westerberg/
Examiner, Art Unit 1618

/MICHAEL G. HARTLEY/
Supervisory Patent Examiner, Art Unit 1618